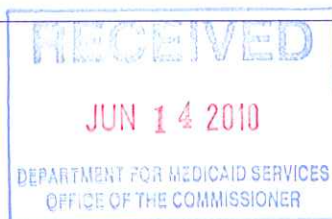




DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

JUN 10 2010



Administrator  
Washington, DC 20201

Ms. Elizabeth A. Johnson  
Commissioner  
Cabinet for Health and Family Services  
275 East Main Street, 6W-A  
Frankfort, KY 40621-0001

6/17/10  
To: Shirley  
Benn  
Lee B.  
From: Betty

Dear Ms. Johnson:

I am responding to your request to approve Kentucky State plan amendment (SPA) 09-010, received by the Centers for Medicare & Medicaid Services (CMS) on October 14, 2009. The SPA would revise the estimated acquisition cost (EAC) formula by increasing reimbursement from average wholesale price (AWP) minus 14 percent for generic drugs and AWP minus 15 percent for brand name drugs to AWP minus 12.25 percent for both brand name and generic drugs. This follows the settlement in the *New England Carpenters Health Benefit Fund v. First DataBank, Inc.* litigation. The SPA would further revise the EAC formula by adding two price points to the algorithm the State applies to determine EAC; wholesale acquisition cost plus 5.5 percent and direct price plus 5.5 percent.

I am unable to approve this SPA because it does not comply with section 1902(a)(30)(A) of the Social Security Act (the Act), which requires, in part, that States have methods and procedures to assure that payments are consistent with efficiency, economy, and quality of care. Under that authority, the Secretary has issued regulations prescribing State rate setting procedures and requirements. Longstanding requirements of Federal regulations presently codified at 42 CFR 447.512 and 42 CFR 447.514 provide that payments for drugs are to be based on the ingredient cost of the drug and a reasonable dispensing fee. States establish their reimbursement methodologies for the ingredient cost of a drug through the EAC. The definition of EAC, presently codified at 42 CFR 447.502 is "the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers."

In support of its proposal, the State indicated that the increase in the EAC is necessary to maintain the current access level to pharmacies for Medicaid beneficiaries. The State expressed concern that the decrease in AWP that resulted from the settlement in the *First DataBank* litigation may cause some pharmacies, particularly rural pharmacies, to be forced out of business. However, the State failed to recognize that the *First DataBank* settlement is intended to correct the previously inflated markup of AWP. As United States District Judge Saris stated in her order approving the settlement, "AWP has been exposed as a faux inflated price unrelated to actual drug prices . . . [and] . . . rolling back AWP's or phasing them out as a pricing benchmark is in the public interest." *New England Carpenters Health Benefit Fund v. First DataBank, Inc.*, (D. Mass. March 17, 2009) (order granting final approval of settlement). The

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State did not demonstrate how access would be adversely affected by keeping the current EAC formula or how the current EAC is inadequate, despite the finding of AWP inflation in the *First DataBank* litigation. In view of these facts, the State has not provided sufficient evidence to support the proposed increase in the EAC. Therefore, I find that this proposed increase in the EAC does not comply with the requirements of section 1902(a)(30)(A) of the Act and Federal regulations defining the EAC.

Based on the above, and after consultation with the Secretary as required by Federal regulations at 42 CFR 430.15(c)(2), I am disapproving Kentucky SPA 09-010. If you are dissatisfied with this determination, you may petition for reconsideration within 60 days after receipt of this letter in accordance with the procedures set forth at 42 CFR 430.18. Your request for consideration may be sent to Ms. Cynthia Hentz, Centers for Medicare & Medicaid Services, Center for Medicaid, CHIP and Survey & Certification, 7500 Security Boulevard, Mail Stop S2-26-12, Baltimore, MD 21244-1850.

If you have any questions or wish to discuss this determination further, please contact Ms. Barbara Edwards, Director, Disabled & Elderly Health Programs Group, Centers for Medicare & Medicaid Services, Center for Medicaid, CHIP and Survey & Certification, 7500 Security Boulevard, Mail Stop S2-14-26, Baltimore, MD 21244-1850.

Sincerely,

A handwritten signature in dark ink, appearing to read "Marilyn Tavenner", with a large, sweeping loop at the end.

Marilyn Tavenner

Acting Administrator and Chief Operating Officer